

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC. &)	
UNIVERSITY OF WASHINGTON,)	
)	
Plaintiffs and)	
Counterclaim Defendants,)	
)	
v.)	Civil Action No. 21-1126-GBW-SRF
)	
GUARDANT HEALTH, INC.,)	
)	
Defendant and)	
Counterclaim Plaintiff.)	

MEMORANDUM ORDER

At Wilmington this **17th** day of **March, 2023**, the court having considered the motion to stay pending inter partes review (“IPR”) filed by defendant Guardant Health, Inc. (“Defendant”) (D.I. 209), IT IS ORDERED that the motion is DENIED for the following reasons:

1. Background. Plaintiffs TwinStrand Biosciences, Inc. and University of Washington (“Plaintiffs”) filed this action on August 3, 2021, asserting infringement of U.S. Patent Nos. 10,287, 631 (“the ’631 patent”); 10,689,699 (“the ’699 patent”); 10,752,951 (“the ’951 patent”); and 10,760,127 (“the ’127 patent;” collectively, the “TwinStrand Asserted Patents”). (D.I. 1) The TwinStrand Asserted Patents claim duplex sequencing methods that allow reliable, early, non-invasive cancer detection and post-treatment cancer monitoring in patients by analyzing blood plasma. (*Id.* at ¶¶ 13, 22)

2. Defendant Guardant Health, Inc. (“Defendant”) filed an answer to the complaint on October 1, 2021, (D.I. 10), and filed an amended answer and counterclaims on January 12, 2022, (D.I. 30). Counterclaims I to IV allege that TwinStrand’s Duplex Sequencing™ kits and methods infringe Defendant’s U.S. Patent Nos. 10,801,063 (“the ’063 patent”), 10,889,858 (“the

'858 patent"), 11,118,221 ("the '221 patent"), and 11,149,306 ("the '306 patent;" collectively, the "Counterclaim Patents"). (D.I. 30 at ¶¶ 134-39, 149-225) The Counterclaim Patents are directed to methods and systems for detecting genetic variants using liquid biopsy cancer assays, which are less painful, less expensive, quicker, and more comprehensive than traditional tumor-based genotyping assays. (*Id.* at ¶¶ 116-20, 130-33)

3. This court previously denied Plaintiffs' motion to sever and stay the claims asserted by Defendant on its Counterclaim Patents on October 28, 2022. (D.I. 145)

4. Plaintiffs and Defendant have each filed multiple IPR petitions before the Patent Trial and Appeal Board ("PTAB") challenging the validity of the Counterclaim Patents and the TwinStrand Asserted Patents, respectively. The focus of the pending motion to stay is on the status of Defendant's IPR petitions against the TwinStrand Asserted Patents. Defendant has filed eight IPR petitions against the four TwinStrand Asserted Patents. (D.I. 211 at ¶ 2) The PTAB instituted proceedings on two of the IPR petitions relating to the '127 patent and the '951 patent, and final written decisions in those proceedings are expected by October 13, 2023 and January 13, 2024, respectively. (*Id.*, Exs. 2-3) The PTAB denied institution on the remaining six IPR petitions, and Defendant has filed requests for rehearing on four of the six petitions. (*Id.* at ¶ 2;¹ D.I. 225 at 9)

5. Plaintiffs also filed six IPR petitions challenging the validity of the Counterclaim Patents. (D.I. 211 at ¶ 3) The PTAB denied institution on five of the petitions and instituted proceedings on the sixth petition pertaining to the '306 patent. (*Id.*; D.I. 227 at 1)

¹ Since briefing on the motion to stay began, the status of the IPR proceedings as outlined in the chart at paragraph 2 of D.I. 211 has changed. The PTAB has denied the petition on IPR2022-01388 pertaining to the '699 patent. Moreover, the PTAB's website indicates that a request for rehearing was filed in IPR2022-01388 on March 2, 2023. See <https://developer.uspto.gov/ptab-web/#/search/documents> (last visited on March 17, 2023).

6. Legal standard. A court has discretionary authority to grant a motion to stay. ⁴⁵⁴ *Life Scis. Corp. v. Ion Torrent Sys., Inc.*, C.A. No. 15-595-LPS, 2016 WL 6594083, at *2 (D. Del. Nov. 7, 2016). Courts consider three factors in deciding how to exercise this discretion: (1) whether a stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage. *Id.* (citing *Advanced Microscopy Inc. v. Carl Zeiss Microscopy, LLC*, C.A. No. 15-516-LPS-CJB, 2016 WL 558615, at *1 (D. Del. Feb. 11, 2016)). This three-factor test “is not a rigid template for decision. Rather, district courts retain the discretionary prerogative to balance considerations beyond those captured by the three-factor stay test.” *TC Tech. LLC v. Sprint Corp.*, C.A. No. 16-153-WCB, 2021 WL 4521045, at *4 (D. Del. Oct. 4, 2021) (internal citations and quotation marks omitted). “[U]ltimately the court must decide stay requests on a case-by-case basis, and whether a stay should be granted turns in each case on the totality of the circumstances.” *See Brit. Telecommc’ns PLC v. IAC / InterActiveCorp.*, C.A. No. 18-366-WCB, 2020 WL 5517283, at *5 (D. Del. Sept. 11, 2020) (internal citations and quotation marks omitted).

7. Analysis. The court has considered the relevant factors in the stay analysis and applied them to the facts of the instant case. On balance, the factors do not weigh in favor of staying this case pending the issuance of final written decisions in the two instituted IPR proceedings.

8. Simplification of issues. This factor is neutral. The PTAB instituted IPR proceedings on every asserted claim for the ’127 and ’951 patents, and it is undisputed that final written decisions favorable to Defendant could invalidate these two patents. (D.I. 211 at ¶ 2; D.I.

225 at 12) But the PTAB’s final written decisions will not address the validity of the two remaining TwinStrand Asserted Patents, nor will they resolve any issues of infringement or invalidity regarding the Counterclaim Patents. The simplification of issues factor does not weigh heavily in favor of a stay when the final written decisions may “simplify some portion of the issues for trial, but would not simplify the majority of the case.” *Siemens Indus., Inc. v. Westinghouse Air Brake Techs. Corp.*, C.A. No. 16-284-LPS, 2018 WL 3046511, at *1 (D. Del. Jun. 20, 2018).

9. Defendant suggests the final written decisions on the ’127 and ’951 patents will be instructive when the court considers the validity of the ’699 and ’631 patents. (D.I. 210 at 9) Similar arguments have been rejected in this district when considered in the context of the numerous other defenses not considered by the PTAB. *See CAO Lighting, Inc. v. Gen. Elec. Co.*, C.A. No. 20-681-GBW, 2022 WL 17752270, at *2 (D. Del. Dec. 19, 2022) (denying motion to stay despite institution of IPR where the defendants could maintain many other defenses in the litigation). Here, the PTAB’s final written decisions will not resolve Defendant’s assertion of invalidity under 35 U.S.C. §§ 101 and 112, improper inventorship, and estoppel, among other defenses. (D.I. 30 at 19-20); *see Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, 193 F. Supp. 3d 345, 349 (D. Del. 2016) (explaining that the PTAB “will not take up any arguments relating to infringement, damages or other issues that will arise in this litigation” regarding non-instituted patents). On balance, any simplification of issues to be gained is outweighed by the remaining factors which do not favor a stay.

10. Status of the litigation. This factor weighs against a stay. In July of 2022, Defendant represented that the stage of the litigation disfavored a stay because the parties had “expended real resources in the case.” (D.I. 82 at 14) (citing *Sound View Innovations, LLC v.*

Cigna Corp., C.A. No. 19-964-CFC-CJB, D.I. 131 (D. Del. Aug. 4, 2020)). Since that time, a Report and Recommendation on claim construction has issued, the deadline for the close of fact discovery has passed, and the parties have exchanged final contentions. (D.I. 190; D.I. 219 at 3) The case has now been pending for more than 18 months, and trial is scheduled to begin in less than eight months. (D.I. 219 at 3) The procedural posture of the case is sufficiently advanced to weigh against a stay. *See President & Fellows of Harvard Coll. v. Micron Tech., Inc.*, C.A. No. 17-1729-LPS-SRF, 2018 WL 10337332, at *1 (D. Del. Jan. 8, 2018); *see also Tr. of Columbia Univ. in the City of N.Y. v. Illumina, Inc.*, C.A. No. 19-1681-CFC-SRF, D.I. 95 (D. Del. Feb. 18, 2021) (denying motion to stay action pending final resolution of IPR proceedings based on findings of undue prejudice and the post-*Markman* stage of the litigation).

11. *Prejudice to the nonmoving party.* Considerations of prejudice to the nonmoving party also weigh against a stay. The court evaluates four factors to determine whether a stay will be prejudicial to Plaintiffs or result in a clear tactical advantage for Defendant: (1) the timing of the request for review; (2) the timing of the request for a stay; (3) the status of the review proceedings; and (4) the relationship of the parties. *See CAO Lighting*, 2022 WL 17752270, at *3.

12. The timing of Defendant's IPR petitions is slightly prejudicial to Plaintiffs. While some of Defendant's IPR petitions were filed within the first few months of the litigation, Defendant waited eight months to file its petitions on the '127 patent and eleven months to file its petitions on the '951 patent. (D.I. 211 at ¶ 2) Defendant cites its compliance with the statutory deadline in support of its diligence. (D.I. 227 at 8) But filing the IPR petitions within the statutory window "does not render [the] request for a stay immune from denial."

TruePosition, Inc. v. Polaris Wireless, Inc., C.A. No. 12-464-RGA-MPT, 2013 WL 5701529, at

*6 (D. Del. Oct. 21, 2013). Defendant offers no reason for waiting many months before filing the only two IPR petitions the PTAB found meritorious.

13. The timing of Defendant's motion to stay supports a finding of prejudice to Plaintiffs. Defendant filed its motion to stay soon after institution was granted on the '951 patent, and Defendant correctly observes that stays are not ordinarily granted before the PTAB has instituted proceedings on an IPR petition. (D.I. 211 at ¶ 2; D.I. 227 at 9) But the PTAB previously instituted proceedings on the '127 patent on October 13, 2022, well before the *Markman* hearing and the close of fact discovery. (D.I. 219 at 3; D.I. 211, Ex. 2) After institution of IPR proceedings on the '127 patent, the parties pursued construction of at least one term which appeared only in the '127 patent. (D.I. 190 at 3) Defendant's position that its chances would be better after waiting for an institution decision on the '951 patent is not compelling. (D.I. 227 at 9) There was no guarantee the PTAB would institute proceedings on the '951 patent, and Defendant's explanation is inconsistent with the fact that it did not wait for an institution decision on the '699 patent, which remained pending at the time the motion to stay was filed. (D.I. 211 at ¶ 2; D.I. 227 at 9) This chain of events gives some traction to Plaintiffs' position that the timing of Defendant's motion to stay was occasioned by the court's Report and Recommendation on claim construction, which was unfavorable to Defendant. (D.I. 225 at 10-11)

14. The status of the IPR proceedings also supports a finding of prejudice. The final written decision on the '127 patent is anticipated by October 13, 2023, several weeks before the scheduled trial. (D.I. 211 at ¶ 2) The final written decision on the '951 patent is due on January 13, 2024, about two months after trial. (D.I. 211 at ¶ 2; D.I. 219 at ¶ 6) If the court were to grant a stay, trial would be delayed by at least a year, and possibly longer, because the decisions will

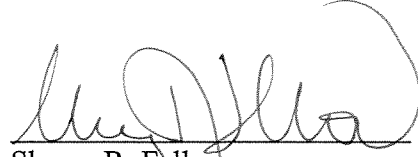
not truly be final until the exhaustion of appellate rights. *See CAO Lighting*, 2022 WL 17752270, at *3; *President & Fellows*, 2018 WL 10337332, at *1.

15. The relationship of the parties supports a finding of inherent prejudice because there is no meaningful dispute that the parties in this case are direct competitors. *See Neste Oil Oyj v. Dynamic Fuels, LLC*, C.A. No. 12-662-GMS, 2013 WL 424754, at *2 (D. Del. Jan. 31, 2013). “[W]hen the parties are direct competitors, there is a reasonable chance that delay in adjudicating the alleged infringement will have outsized consequences to the party asserting infringement has occurred, including the potential for loss of market share and an erosion of goodwill.” *SenoRx, Inc. v. Hologic, Inc.*, C.A. No. 12-173-LPS-CJB, 2013 WL 144255, at *8 (D. Del. Jan. 11, 2013). As Defendant previously observed when opposing Plaintiffs’ motion to sever and stay, any stay of the infringement claims in this case would prejudice Defendant because it would permit Plaintiffs to continue selling infringing products. (D.I. 82 at 6) There is no reason to assume that the same conclusion should not apply when Defendant is the movant.

16. Conclusion. For the foregoing reasons, Defendant’s motion to stay pending IPR is DENIED. (D.I. 209)

17. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to four (4) pages each.

18. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, www.ded.uscourts.gov.


Sherry R. Fallon
United States Magistrate Judge